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## Condensed Transcript

In the Matter Of:

NEW ENGLAND COMPOUNDING PHARMACY INC. PRODUCTS LIABILITY

VIDEOTAPED DEPOSITION OF

JAMES D. CATHEY

*March 09, 2016*



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Page 1

1 UNITED STATES DISTRICT COURT  
2 DISTRICT OF MASSACHUSETTS  
3  
4

5 IN RE: NEW ENGLAND COMPOUNDING  
6 PHARMACY, INC. PRODUCTS LIABILITY  
7 LITIGATION

8 MDL No. 2419

9 Docket No. 1:13-md-2419 (RWZ)  
10

11 THIS DOCUMENT RELATES TO:  
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13  
14

15 ALL CASES  
16  
17

18 VIDEOTAPED DEPOSITION  
19 BY WRITTEN QUESTIONS OF  
20 JAMES D. CATHEY  
21 March 9, 2016  
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Pages 2..5

Page 2	Page 4
<p>1 APPEARANCES:</p> <p>2 FOR THE EAST TENNESSEE CHILDREN'S HOSPITAL:</p> <p>3 BRUCE ANDERSON, ESQUIRE</p> <p>4 Vice President Legal Services</p> <p>5 General Counsel</p> <p>6 2018 Clinch Avenue</p> <p>7 Knoxville, Tennessee 37916-2301</p> <p>8 INDEX</p>	<p>1 STIPULATION</p> <p>2 The video-taped deposition of James D. Cathey, called</p> <p>3 as a witness, taken pursuant to Rule 31, of the Federal Rules of</p> <p>4 Civil Procedure, and taken by agreement on the 8th day of March,</p> <p>5 2016, at the offices of Children's Hospital, 2018 Clinch Avenue,</p> <p>6 Administrative Conference Room, Knoxville, Tennessee, before</p> <p>7 Verna Mansfield,</p> <p>8 VIDEOGRAPHER: Okay. We are on the record. This is tape</p> <p>9 number one to the video deposition of Mr. Jim Cathey, taken in</p> <p>10 the matter of New England Compounding Pharmacies, Incorporated,</p> <p>11 product litigation -- product liability litigation, excuse me.</p> <p>12 This deposition is being held at the Children's Hospital in</p> <p>13 Knoxville, Tennessee. Today's date is March 9th, 2016, and the</p> <p>14 time on the camera is 10:01 a.m. My name is Eric Tracey; I'm</p> <p>15 the videographer. The court reporter is Mrs. Verna Maxwell</p> <p>16 (sic), and counsel will now identify themselves for the record.</p> <p>17 MR. ANDERSON: Okay. This is Bruce Anderson and I am the</p> <p>18 vice-president for legal services and general counsel for East</p> <p>19 Tennessee Children's Hospital.</p> <p>20 Before we begin, if it's okay, I'd like to make a comment</p> <p>21 on the record. We have received these questions in advance and</p> <p>22 Mr. Cathey has had a chance to review those. A lot of the</p> <p>23 questions ask him to read out loud articles and we see no</p> <p>24 purpose in doing that. We'll stipulate at the time that the</p> <p>25 article says whatever it says and then he can answer the</p>
Page No.	
<p>11 Examination, . . . . . 5</p> <p>12 Written questions by Premier</p> <p>13 Examination, . . . . . 11</p> <p>14 Written questions by 10 Key Defendants</p>	
Page 3	Page 5
<p>1 EXHIBITS</p> <p>2</p> <p>3 Exhibit 1-----12</p> <p>4 Notes</p> <p>5 Exhibit 2-----17</p> <p>6 Sutton Article, "GMP &amp; Compounding Pharmacies"</p> <p>7 Exhibit 3-----22</p> <p>8 Consent Order</p> <p>9 Exhibit 4-----23</p> <p>10 Warning Letter</p> <p>11 Exhibit 5-----27</p> <p>12 Sellers Article, "Pharmacy Compounding Primer for</p> <p>13 Physicians"</p> <p>14 Exhibit 6-----28</p> <p>15 J. G. Whelan Article "Subpotency of a</p> <p>16 Compounded Budesonide for a Nebulization Product</p> <p>17 in a Patient w/ Poorly Controlled Asthma</p> <p>18 Exhibit 7-----29</p> <p>19 USP Gap Analysis Tool</p>	<p>1 question related to that article, but to simply read these out</p> <p>2 loud seems to serve no purpose other than taking his time away</p> <p>3 from taking care of the kids here at the hospital. So I just</p> <p>4 want everybody to be aware of how we're going to handle that in</p> <p>5 advance.</p> <p>6 EXAMINATION</p> <p>7 BY WRITTEN QUESTIONS:</p> <p>8 JAMES D. CATHEY,</p> <p>9 Called as a witness, being first duly sworn was examined</p> <p>10 and testified as follows:</p> <p>11 Q. Please state your name.</p> <p>12 A. My name is James D. Cathey.</p> <p>13 Q. Please provide your complete address and phone number</p> <p>14 with the area code.</p> <p>15 A. My address is 2109 Woodmere Lane, Knoxville, Tennessee</p> <p>16 37902. My phone number is 865-579-6355.</p> <p>17 Q. Do you work at East Tennessee Children's Hospital?</p> <p>18 A. Yes.</p> <p>19 Q. What is your current position?</p> <p>20 A. Pharmacy director.</p> <p>21 Q. How long have you held that position?</p> <p>22 A. Ten years.</p> <p>23 Q. Please describe your job duties at East Tennessee</p> <p>24 Children's Hospital.</p> <p>25</p>



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Pages 6..9

Page 6	Page 8
<p>1 A. I manage the pharmacy operations. I manage a staff of 2 roughly 62 people. We provide clinical services and 3 distributive drug services to the children of your hospital. 4 Q. Please provide a brief summary of your educational and 5 employment background, leading up to your present position at 6 East Tennessee Children's Hospital. 7 A. I graduated from the University of Tennessee College 8 of Pharmacy in 1972. I have been in positions in pharmacy since 9 that time that have included a teaching position at LeBonheur. 10 I started as a pharmacist at LeBonheur and as I finished my 11 time, 23 years at LeBonheur, I ended it not in pharmacy, I was 12 director of peri-operative services, but I spent -- out of 23 13 years, I spent roughly 20 of those years in pharmacy that took 14 me to assistant director. 15 I was also director of the outpatient pharmacy that we 16 opened. I have been pharmacy director at Bedford County General 17 Hospital for a year and a half. I have also been assistant 18 director of pharmacy at St. Jude Children's Research Hospital in 19 Memphis, Tennessee for five years, and then I have been here for 20 ten. 21 Probably the first year that I was out of school, from 1972 22 to '73 I worked for Super X Retail Drugs in Cookeville, 23 Tennessee. 24 Q. Please provide a general description of your facility. 25 A. We are a 152 bed hospital. We've got somewhere</p>	<p>1 medications were purchased. 2 A. We purchased medications starting in August of 2010. 3 The last purchase order was placed on October 2nd of 2012. 4 These included eight drugs, and I don't have the list in front 5 of me, but they did include the Ciprofloxacin and Dexamethasone 6 ear drops. They included Lasix, they included other 7 single-entity injectable drugs, and one multi-dose vial of a 8 drop that was used by our ophthalmologist in his office 9 practice. 10 Q. Prior to purchasing medications from NECC, did a 11 representative of East Tennessee Children's Hospital perform an 12 in-person inspection of NECC's compounding facility? 13 A. No. 14 Q. Prior to purchasing medications from NECC, did East 15 Tennessee Children's Hospital conduct research into whether NECC 16 had recalled any medications made by NECC? 17 A. No. 18 Q. Prior to purchasing medications from NECC, did East 19 Tennessee Children's Hospital conduct research into whether NECC 20 had ever been named as a defendant in a products liability 21 lawsuit? 22 A. No. 23 Q. Prior to purchasing medications from NECC, did East 24 Tennessee Children's Hospital request information from the 25 Massachusetts Board of Registration in Pharmacy, the "Board"</p>
Page 7	Page 9
<p>1 roughly between 300 and 400 physicians that have attending 2 privileges here. We've got in the neighborhood of 20 to 22 3 clinical specialties that we provide for our patients. We are a 4 community children's hospital that serves the East Tennessee 5 region. 6 Q. By virtue of your role at East Tennessee Children's 7 Hospital, are you familiar with East Tennessee Children's 8 Hospital's medication purchasing practices? 9 A. I am. 10 Q. Please describe the basis for your familiarity with 11 East Tennessee Children's Hospital's medication purchasing 12 practices; example, is it from personal knowledge? Have you 13 spoken with persons at East Tennessee Children's Hospital or 14 reviewed documents? 15 A. As the pharmacist in charge for East Tennessee 16 Children's Hospital pharmacy, I'm directly responsible for 17 purchasing as part of my job description. 18 Q. For the years 2010 through 2012, did East Tennessee 19 Children's Hospital purchase medications offered for sale by 20 Medical Sales Management and/or New England Compounding Center 21 and made by the New England Compounding Center, hereinafter 22 referred to as "NECC"? 23 A. Yes. 24 Q. Please describe the timeframes that East Tennessee 25 Children's Hospital purchased medications from NECC and what</p>	<p>1 about previous disciplinary actions taken by the Board against 2 NECC? 3 A. No. 4 Q. Prior to purchasing medications from NECC, did East 5 Tennessee Children's Hospital submit a Freedom of Information 6 Act request to the FDA for documentation of disciplinary actions 7 and/or warnings issued to NECC by the FDA? 8 A. No. 9 Q. Prior to purchasing medications from NECC, did East 10 Tennessee Children's Hospital search the FDA website for 11 information about NECC? 12 A. No. 13 Q. Prior to purchasing medications from NECC, did East 14 Tennessee Children's Hospital review transcripts from or 15 summaries of any U.S. Congressional hearings on compounding 16 pharmacies? 17 A. No. 18 Q. At the time of East Tennessee Children's Hospital's 19 purchases from NECC, did East Tennessee Children's Hospital have 20 a policy and/or procedure in place prohibiting purchases from 21 compounding pharmacies? 22 A. No. 23 Q. Please describe any representations Medical Sales 24 Management and/or NECC made to East Tennessee Children's 25 Hospital prior to East Tennessee Children's Hospital purchasing</p>



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Pages 10..13

<p style="text-align: right;">Page 10</p> <p>1 medications from NECC.</p> <p>2 A. NECC negotiated contracts with a buying group that</p> <p>3 represented many of the children's hospitals. That buying group</p> <p>4 was called Child Health Corporation of America, and once they</p> <p>5 were approved to provide those services, we entered into an</p> <p>6 agreement with NECC, based on them being an approved vendor.</p> <p>7 Q. In deciding to purchase medications from NECC, did</p> <p>8 East Tennessee Children's Hospital take into consideration any</p> <p>9 representations from Medical Sales Management and/or NECC</p> <p>10 regarding its ability to provide a consistent supply of safe</p> <p>11 medications?</p> <p>12 A. This was one of the conditions that allowed them to</p> <p>13 win the award with the Child Health Corporation of America,</p> <p>14 because they gave evidence to our purchasing group that they</p> <p>15 could provide the supply.</p> <p>16 Q. Prior to purchasing from NECC, did East Tennessee</p> <p>17 Children's Hospital research compounding pharmacies in CDC</p> <p>18 literature, USA TODAY, FDA literature, or on YouTube?</p> <p>19 A. No.</p> <p>20 Q. To the best of your knowledge, did any of East</p> <p>21 Tennessee Children's Hospital's patients experience an injury as</p> <p>22 a result of East Tennessee Children's Hospital's purchase, and</p> <p>23 use, of medications from NECC which were administered to East</p> <p>24 Tennessee Children's Hospital's patients?</p> <p>25 A. No.</p>	<p style="text-align: right;">Page 12</p> <p>1 Q. Did you or your attorney have any conversations or</p> <p>2 other communications with any of the attorneys representing Box</p> <p>3 Hill, Premier or Saint Thomas Outpatient Neurosurgical Center?</p> <p>4 A. I have not.</p> <p>5 Q. Did you or your attorney have any conversations or</p> <p>6 other communications with any insurers of Box Hill, Premier, or</p> <p>7 Saint Thomas Outpatient Neurosurgical Center?</p> <p>8 A. I have not.</p> <p>9 Q. Did you or your attorney have any conversations or</p> <p>10 other communications with any person employed or associated with</p> <p>11 Box Hill, Premier, or Saint Thomas Outpatient Neurosurgical</p> <p>12 Center?</p> <p>13 A. I have not.</p> <p>14 Q. Do you have with you any written answers or written</p> <p>15 notes to answer the written questions which were served upon</p> <p>16 you?</p> <p>17 A. I've got one or two annotations on this document that</p> <p>18 I can give you.</p> <p>19 MR. ANDERSON: And this document being the written</p> <p>20 questions that were provided previously.</p> <p>21 COURT REPORTER: I need to mark that as Exhibit 1.</p> <p>22 (The notes were marked as Exhibit No. 1.)</p> <p>23 Q. What documents did you review in preparing your</p> <p>24 answers or notes to the written questions served upon you?</p> <p>25 A. I reviewed Exhibit 3, the deposition packet.</p>
<p style="text-align: right;">Page 11</p> <p>1 (The following questions are submitted by the plaintiff</p> <p>2 steering committee.)</p> <p>3 Q. When did you receive the written deposition questions</p> <p>4 that were served upon you?</p> <p>5 A. These deposition questions came to me a week ago this</p> <p>6 past Monday.</p> <p>7 Q. As this is a deposition upon written questions, you</p> <p>8 have been provided in advance with every question that will be</p> <p>9 asked of you today, correct?</p> <p>10 A. Yes.</p> <p>11 Q. Is it correct that you had an opportunity to consult</p> <p>12 with an attorney in drafting the answers of those written</p> <p>13 questions?</p> <p>14 A. I reviewed what we would do, with Bruce Anderson, our</p> <p>15 vice-president of legal services.</p> <p>16 Q. And an attorney assisted you in preparing answers to</p> <p>17 the written questions, correct?</p> <p>18 A. He prepared me for this meeting.</p> <p>19 Q. What is the attorney's name?</p> <p>20 A. Bruce Anderson.</p> <p>21 Q. And you understand that one of the limitations of a</p> <p>22 deposition upon written questions is that we do not know what</p> <p>23 your answers will be when we drafted the questions that we</p> <p>24 submitted?</p> <p>25 A. I understand.</p>	<p style="text-align: right;">Page 13</p> <p>1 Q. Did anyone assist you in preparing these written</p> <p>2 answers or notes?</p> <p>3 A. No.</p> <p>4 Q. If I understand it correctly, East Tennessee</p> <p>5 Children's Hospital, which I will refer to as "ETCH," ordered</p> <p>6 seven types of drugs from NECC, correct?</p> <p>7 A. We ordered eight.</p> <p>8 Q. What drugs did you purchase?</p> <p>9 A. I can provide that list. I don't have them here.</p> <p>10 Q. During what years did you purchase each one?</p> <p>11 A. From August of 2010 through September -- actually our</p> <p>12 last purchase was October of 2012.</p> <p>13 Q. Is it correct that ETCH never purchased any</p> <p>14 preservative-free --</p> <p>15 A. Methylprednisolone acetate.</p> <p>16 Q. -- methylprednisolone acetate, which I refer to as</p> <p>17 "MPA" from NECC?</p> <p>18 A. Correct.</p> <p>19 Q. ETCH placed an order Ciprofloxacin/Dexamethasone</p> <p>20 0.3%/0.1% Suspension, 1 ML dropper in September 2012, correct?</p> <p>21 A. Correct.</p> <p>22 Q. What is this drug used for?</p> <p>23 A. It is an ear drop that contains an antibiotic and a</p> <p>24 steroid that is used after ENT, ear, nose and throat surgery, to</p> <p>25 prevent infection and to reduce inflammation and swelling.</p>



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